



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: ANNA P. CATANIA *ET AL.*
APPLICATION No.: 10/659,053
FILED: SEPTEMBER 8, 2003
FOR: **A COMPOSITION AND METHOD OF TREATMENT
FOR UROGENITAL CONDITIONS**

EXAMINER:
ART UNIT:
CONF. No:

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. Timing of Submission

This information disclosure is being filed within three months of the filing date of this application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever occurs last [37 C.F.R. § 1.97(b)]. The references listed on the enclosed Form PTO-1449 (modified) may be material to the examination of this application; the Examiner is requested to make them of record in the application.

2. Cited Information

Copies of references marked by asterisks (i.e. A14, A15, and A16) have not been cited previously in the parent application. Because this application was filed after 30 June 2003, no copies of these U.S. patents are enclosed (See Notice of Deputy Commissioner Kunin on 11 July 2003).

Copies of all references not marked by asterisks can be found in parent U.S. Application No. 09/535,066 and/or in U.S. Application No. 10/442,683 to which Applicant also claimed priority.

Certificate of Mailing

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

February 5, 2004
Date of Deposit

Debbie Gilbert
Debbie Gilbert

3. Effect of Information Disclosure Statement (37 C.F.R. § 1.97(h))

This Information Disclosure Statement is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the cited information is, or is considered to be, material to patentability. In addition, applicant does not admit that any enclosed item of information constitutes prior art to the subject invention and specifically reserves the right to demonstrate that any such reference is not prior art.

4. Fee Payment

No fees are believed due because this Information Disclosure Statement is being filed before the mailing date of the first Office Action.

However, should the Commissioner determine that fees are due in order for this Information Disclosure Statement to be considered, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-2586.

Dated: 2/5, 2004

Respectfully submitted,

Customer No. 34055
Perkins Coie LLP
Patent - LA
P.O. Box 1208
Seattle, WA 98111-1208
Phone: (310) 788-9900
Fax: (310) 788-3399

PERKINS COIE LLP

By: 

David P. Devlin
Reg. No. P55,876

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Form PTO-1449 (Modified)
(Use several sheets if necessary)

FEB 09 2004

COMPLETE IF KNOWN

| | |
|----------------------|-------------------|
| Application Number | 10/659,053 |
| Confirmation Number | |
| Filing Date | September 8, 2003 |
| First Named Inventor | James M. LIPTON |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket No. | 54275.8005.US03 |

Sheet

1

of

11

U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. | U.S. Patent or Application | | Name of Patentee or Inventor of Cited Document | Date of Publication or Filing Date of Cited Document | Pages, Columns, Lines, Where Relevant Figures Appear |
|----------------------|-------------|----------------------------|-------------------------|---|--|--|
| | | NUMBER | Kind Code (if known) | | | |
| | A1 | 09/533,341 | | Catania Anna P. et al. | 03/23/00 | |
| | A2 | 09/957,765 | | Catania Anna P. et al. | 09/21/01 | |
| | A3 | US-2002/0137685 | | Catania et al. | 09/21/01 | |
| | A4 | 60/200,287 | | Lipton, J.M. | 04/28/00 | |
| | A5 | 09/774,282 | | Lipton, J.M. | 01/29/01 | |
| | A6 | 09/828,272 | | Lipton, J.M. | 04/06/01 | |
| | A7 | 09/704,327 | | Lipton, J.M. | 11/01/00 | |
| | A8 | 5,028,592 | | Lipton, J.M. | 08/05/88 | |
| | A9 | 5,157,023 | | Lipton, J.M. | 03/21/91 | |
| | A10 | US-2002/0146374 | | Lipton | 01/29/01 | |
| | A11 | US-2002/0183255 | | Lipton et al. | 04/06/01 | |
| | A12 | 5,739,111 | | Mahe, Yann | 04/29/96 | |
| | A13 | 6,001,812 | | Mahe, Yann | 01/23/98 | |
| | *A14 | 3,247,182 A | | Schwyzer et al. | 11/15/61 | |
| | *A15 | 3,300,468 A | | Schwyzer et al. | 05/13/64 | |
| | *A16 | 4,918,055 A | | Hruby et al. | 02/11/88 | |
| | A17 | 09/535,066 | | Lipton et al. | 03/23/00 | |
| | A18 | 10/420,578 | | Lipton et al. | 04/21/03 | |
| | A19 | 10/426,647 | | Lipton et al. | 04/29/03 | |
| | A20 | 10/298,142 | | Lipton | 11/15/02 | |

FOREIGN PATENT DOCUMENTS

| Examiner Initial | Cite No. | Foreign Patent or Application | | | Name of Patentee or Applicant of Cited Document | Date of Publication or Filing Date of Cited Document | Pages, Columns, Lines, Where Relevant Figures Appear | T |
|---------------------|-------------|-------------------------------|----------------|-------------------------|--|--|--|---|
| | | Office | NUMBER | Kind Code (if known) | | | | |
| | B1 | | EP 0972 522 A1 | | Mahe et al. | 01/19/00 | | |
| | B2 | | FR 2,784,028 | | | 04/07/00 | | |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s).

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Form PTO-1449 (Modified)
(Use several sheets if necessary)



COMPLETE IF KNOWN

| | |
|----------------------|-------------------|
| Application Number | 10/659,053 |
| Confirmation Number | |
| Filing Date | September 8, 2003 |
| First Named Inventor | James M. LIPTON |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket No. | 54275.8005.US03 |

| | | | |
|-------|---|----|----|
| Sheet | 2 | of | 11 |
|-------|---|----|----|

| | | | | | |
|----|----------------|-------------------|----------|--|--|
| B3 | WO 97/10838 | Mahe et al. | 03/27/97 | | |
| B4 | WO 93/01211 | Rathjen et al. | 01/21/93 | | |
| B5 | PCT/US00/07846 | | 03/23/00 | | |
| B6 | WO 99/58101 | Jarroussee et al. | 11/18/99 | | |
| B7 | WO 00/42856 | Taylor et al. | 07/27/00 | | |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| <p>*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s).</p> | |

| | | | | | |
|---|-----------------|----|----|--------------------------|-------------------|
| <p align="center">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p align="center">Form PTO-1449 (Modified) (Use several sheets if necessary)</p> | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/659,053 |
| | | | | Confirmation Number | |
| | | | | Filing Date | September 8, 2003 |
| | | | | First Named Inventor | James M. LIPTON |
| | | | | Group Art Unit | |
| Examiner Name | | | | | |
| Attorney Docket No. | 54275.8005.US03 | | | | |
| Sheet | 3 | of | 11 | | |

| OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS | | | | |
|---|----------|---|--|--|
| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published. | | |
| | C1 | AIRAGHI, L., <i>et al.</i> , "Elevated concentrations of plasma α -MSH are associated with reduced disease progression in HIV-infected patients," <i>J. Lab. Clin. Med.</i> 133(3) 309-315 (1999). | | |
| | C2 | AIRAGHI L., <i>et al.</i> , "Endogenous cytokine antagonists during myocardial ischemia and thrombolytic therapy." <i>Am. Heart J.</i> 130: 204-211, (1995). | | |
| | C3 | AIRAGHI L., <i>et al.</i> , "Plasma concentrations of α -melanocyte-stimulating hormone are elevated in patients on chronic haemodialysis," <i>Nephrology Dialysis Transplantation</i> 15:1212-1216, (2000). | | |
| | C4 | ARMSTRONG, "The Microbiology of the Eye." <i>Ophthalm. Physiol. Opt.</i> 20: 429-503 (2000). | | |
| | C5 | AYLAD <i>et al.</i> , "Influence of Oral Acyclovir on Ocular Complications of <i>Herpes zoster ophthalmicus</i> ." <i>Eye</i> 8: 70-74 (1994). | | |
| | C6 | BAKER, M., <i>et al.</i> , "The Relationship between Interleukin-6 and Herpes Simplex Virus Type-1: Implications for Behavior and Immunopathology," <i>Brain Behav. Immun.</i> 13(3):201-11 (1999). | | |
| | C7 | BAKER, <i>et al.</i> , "Principles of Ambulatory Medicine," <i>Williams and Wilkins</i> (1982). | | |
| | C8 | BARCELLINI, W., <i>et al.</i> , "Inhibitory Influences of α -MSH peptides on HIV-1 expression in Monocytic cells," <i>12th World AIDS Conference Geneva</i> , Abstract No. 60685, June 28-July 3, (1998). | | |
| | C9 | BARCELLINI W., <i>et al.</i> , " α -MSH peptides inhibit HIV-1 expression in chronically infected promonocytic U1 cells and in acutely infected monocytes," <i>Journal of Leukocyte Biology</i> 68:693-699, (2000). | | |
| | C10 | BHATTACHARYA A., <i>et al.</i> , "Effect of Cyclic AMP on RNA and Protein Synthesis in <i>Candida albicans</i> ," <i>Biochem, Biophysics. Res. Commun.</i> , 77: 1438-44 (1977). | | |
| | C11 | BICKERS, D., "Sun-Induced Disorders," <i>Emergency Medicine Clinics of North America</i> , 3(4): 659-663, 660 (1985). | | |
| | C12 | CAPSONI, F., <i>et al.</i> , "Effect of Corticosteroids on Neutrophil Function: Inhibition of Antibody-dependent Cell-Mediated Cytotoxicity (ADCC)," <i>J. Immunopharmacol.</i> 5, 217-30 (1983). | | |
| | C13 | CARTLEDGE, J.D., <i>et al.</i> , "Clinically Significant Azole Cross-Resistance in <i>Candida</i> Isolates from HIV-Positive Patients with Oral Candidosis," <i>AIDS</i> 11:1839-44 (1997). | | |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| <p>*EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s).</p> | |

| | | | | | |
|---|---|----|----|--------------------------|-------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary) | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/659,053 |
| | | | | Confirmation Number | |
| | | | | Filing Date | September 8, 2003 |
| | | | | First Named Inventor | James M. LIPTON |
| | | | | Group Art Unit | |
| Examiner Name | | | | | |
| Sheet | 4 | of | 11 | Attorney Docket No. | 54275.8005.US03 |

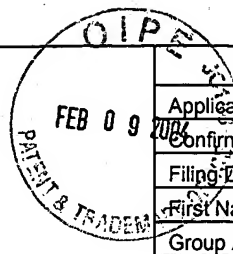
| | |
|-----|--|
| C14 | CATANIA, A., <i>et al.</i> , "α-Melanocyte Stimulating Hormone in the Modulation of Host Reactions," <i>Endocr. Rev.</i> 14, 564-576 (1993). |
| C15 | CATANIA, A., <i>et al.</i> , "Melanocortin Peptides Inhibit Production of Proinflammatory Cytokines in Blood of HIV-Infected Patients," <i>Peptides</i> , 19(6): 1099-1104 (1998). |
| C16 | CATANIA, A., <i>et al.</i> , "The Neuropeptide α-MSH in HIV Infection and Other Disorders in Humans," <i>Ann. N.Y. Acad. Sci.</i> 840: 848-856 (1998). |
| C17 | CATANIA, A., <i>et al.</i> , "The Neuropeptide α-MSH has Specific Receptors on Neutrophils and Reduces Chemotaxis in Vitro," <i>Peptides</i> 17, 675-679 (1996). |
| C18 | CATANIA, A., <i>et al.</i> , "α-MSH in normal human physiology and disease states," <i>Trends Endocrinol. Metab.</i> 11:304-308, (2000). |
| C19 | CATANIA, A., <i>et al.</i> , "α-MSH in systemic inflammation: central and peripheral actions," <i>Annals of the New York Academy of Sciences</i> , 885:183-187, (1999). |
| C20 | CATANIA, A., <i>et al.</i> , "Cytokine antagonists in infectious and inflammatory disorders," <i>Annals of the New York Academy of Sciences</i> 741: 149-161, (1994). |
| C21 | CATANIA, A., <i>et al.</i> , "α-melanocyte-stimulating hormone peptides in host responses: from basic evidence to human research," <i>Annals of the New York Academy of Sciences</i> 680: 412-423, (1993). |
| C22 | CATANIA, A., <i>et al.</i> , "Plasma concentrations and anti-L-cytokine effects of α-melanocyte stimulating hormone in septic patients," <i>Crit. Care Med.</i> 28: 1403-1407, (2000). |
| C23 | CATANIA, A., <i>et al.</i> , "Cytokine antagonists in aged subjects and their relation with cellular immunity," <i>Journal of Gerontology: Biological Sciences</i> 52A: B93-97, (1997). |
| C24 | CATANIA, A., <i>et al.</i> , "Plasma concentration of cytokine antagonists in patients with HIV infection," <i>Neuroimmunomodulation</i> 1: 42-49, (1994). |
| C25 | CATANIA, A., <i>et al.</i> , "Proopiomelanocortin-derived peptides and cytokines: relations in patients with acquired immunodeficiency syndrome," <i>Clinical Immunology and Immunopathology</i> 66: 73-79, (1993). |
| C26 | CAVELLO, J., <i>et al.</i> , "Sunburn," <i>Dermatologic Clinics</i> , 4(2): 181-187, 181 (1986). |
| C27 | CERIANI, G., <i>et al.</i> , "Central Neurogenic Antiinflammatory Action of α-MSH: Modulation of Peripheral Inflammation Induced by Cytokines and other Mediators of Inflammation," <i>Neuroendocrinology</i> , 59:138-143 (1994). |
| C28 | CERIANI, G., <i>et al.</i> , "The neuropeptide alpha-melanocyte-stimulating hormone inhibits experimental arthritis in rats," <i>Neuroimmunomodulation</i> 1:28-32, (1994). |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s). | |

| | | | | | | |
|---|-----------------|----|----|--------------------------|-------------------|--|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary) | | | | COMPLETE IF KNOWN | | |
| | | | | Application Number | 10/659,053 | |
| | | | | Confirmation Number | | |
| | | | | Filing Date | September 8, 2003 | |
| | | | | First Named Inventor | James M. LIPTON | |
| | | | | Group Art Unit | | |
| Examiner Name | | | | | | |
| Attorney Docket No. | 54275.8005.US03 | | | | | |
| Sheet | 5 | of | 11 | | | |

| | |
|-----|---|
| C29 | CHIAO, H., <i>et al.</i> , "α-MSH reduces endotoxin-induced liver inflammation," <i>J. Clin. Invest.</i> 97: 2038-2044, (1996). |
| C30 | CSATA, M., <i>et al.</i> , "Enhancement of <i>Candida albicans</i> killing activity of separated human epidermal cells by alpha-melanocyte stimulating hormone," <i>British Journal of Dermatology</i> , 121(1) 145-147 (1989). |
| C31 | CUTULI, M., <i>et al.</i> , "Antimicrobial effects of α-MSH peptides," <i>Journal of Leukocyte Biology</i> 67:233-239 (2000). |
| C32 | DEETER, L.B., <i>et al.</i> , "Antipyretic Properties of Centrally Administered α-MSH Fragments in the Rabbit," <i>Peptides</i> 9, 1285-1288 (1989). |
| C33 | DELGADO, R., <i>et al.</i> , "Melanocortin peptides inhibit production of proinflammatory cytokines and nitric oxide by activated microglia," <i>Journal of Leukocyte Biology</i> , 63: 740-745 (1998). |
| C34 | DOMK-OPTIZ, I., <i>et al.</i> , "Stimulation of Macrophages by Endotoxin Results in the Reactivation of a Persistent Herpes Simplex Virus Infection," <i>Scand J. Immunol.</i> 32(2):69-75 (1990). |
| C35 | DOUGHTERY <i>et al.</i> , "The Role of Tetracycline in Chronic Blepharitis: Inhibition of Lipase Production in <i>Staphylococcus</i> ." <i>Inv. Ophthalmol. Vic. Sci.</i> 32: 2970-2975 (1991). |
| C36 | EBERLE, A., <i>et al.</i> , "Hormone-Receptor Interactions, The Message Sequence of α-Melanotropin: Demonstration of Two Active Sites," <i>Clinical Endocrinology</i> 5, Suppl., 41s-48s (1976). |
| C37 | EBERLE, A.N., "The Melanotrophins," <i>Karger, Basel, Switzerland</i> (1988). |
| C38 | FAUCHERE, <i>et al.</i> , "Potentiation of the antagonistic effect of ACTH ₁₁₋₂₄ on steroidogenesis by synthesis of covalent dimeric conjugates." <i>FEBS</i> 2469, 183(2): 283-286 (1985). |
| C39 | FAUCHERE, <i>et al.</i> , "Synthesis and Antagonistic Activity of Two Covalently Linked Dimers of Adrenocorticotropin-(11-24)-tetradcapeptide." <i>Helvetica Chimica ACTA</i> 68: 770-776 (1985). |
| C40 | FAUCI, A.S., "Host Factors and the Pathogenesis of HIV-induced Disease," <i>Nature</i> 384: 529 (1996). |
| C41 | FEUILLOLEY, <i>et al.</i> , "Structure-Activity Relationships of Monomeric and Dimeric Synthetic ACTH Fragments in Perfused Frog Adrenal Slices." <i>J. steroid Biochem</i> 35(5): 583-592 (1990). |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s). | |



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Form PTO-1449 (Modified)
(Use several sheets if necessary)

COMPLETE IF KNOWN

| | |
|----------------------|-------------------|
| Application Number | 10/659,053 |
| Confirmation Number | |
| Filing Date | September 8, 2003 |
| First Named Inventor | James M. LIPTON |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket No. | 54275.8005.US03 |

| | | | |
|-------|---|----|----|
| Sheet | 6 | of | 11 |
|-------|---|----|----|

| | |
|-----|---|
| C42 | FITZPATRICK, <i>et al.</i> , "Acute Effects of Ultraviolet Radiation on the Skin: The Sunburn Reaction," <i>Dermatology in General Medicine</i> , 4th Edition, 1651-1655, 1651 (1993). |
| C43 | FITZPATRICK, <i>et al.</i> , "Color Atlas and Synopsis of Clinical Dermatology," (1983). |
| C44 | FOSTER, J., "Sunburn," <i>eMedicine – Online Medical Reference Textbook</i> , (last modified May 1, 2000). < http://emedicine.com/emerg/topic798.htm . |
| C45 | FOX, J. A., <i>et al.</i> , "Immunoreactive α -Melanocyte Stimulating Hormone, Its Distribution in the Gastrointestinal Tract of Intact and Hypophysectomized Rats," <i>Life. Sci.</i> 28, 2127-2132 (1981). |
| C46 | GALIMBERTI, D., <i>et al.</i> , " α -MSH peptides inhibit production of nitric oxide and tumor necrosis factor- α by microglial cells activated with β -amyloid and interferon γ ," <i>Biochemical Biophysical Research Communications</i> 263: 251-256,(1999). |
| C47 | GETTING, <i>et al.</i> , "POMC Gene-Derived Peptides Activate Melanocortin Type 3 Receptor on Murine Macrophages, Suppress Cytokine Release, and Inhibit Neutrophil Migration in Acute Experimental Inflammation," <i>J. Immunol.</i> , vol. 162, No. 12, pgs. 7446-7453 (1999). |
| C48 | HARRIS, <i>et al.</i> , "Alpha-melanocyte stimulating hormone (α -MSH) and melanin-concentrating hormone (MCH) stimulate phagocytosis by head kidney leucocytes of rainbow trout (<i>Oncorhynchus mykiss</i>) in vitro," <i>Fish & Shell Immunol.</i> , Vol. 8, 8:631-638 (1998). |
| C49 | GOW, N.A., "Germ Tube Growth of <i>Candida albicans</i> ," <i>Curr. Topics Med. Myco.</i> 8, 43-55 (1997). |
| C50 | HART, D.A., <i>et al.</i> , " <i>Staphylococcus Aureus</i> Strains Differ in Their in Vitro Responsiveness to Human Urokinase: Evidence that Methicillin-Resistant Strains are Predominantly Nonresponsive to the Growth-Enhancing Effects of Urokinase," <i>Can. J. Microbiol.</i> 42: 1024-31 (1966). |
| C51 | "Harry's Comseticology", <i>Chemical Publishing</i> , 7 th ed. (1982). |
| C52 | HILTZ, M. E., <i>et al.</i> , "Anti-inflammatory Activity of a COOH-terminal Fragment of the Neuropeptide α -MSH," <i>FASEB J.</i> 3, 2282-2284 (1989). |
| C53 | HILTZ, M.E., "Anti-inflammatory Activity of α -MSH (11-13) Analogs: Influences of Alterations in Stereochemistry," <i>Peptides</i> 12, 767-71 (1991). |
| C54 | HILTZ, M.E., <i>et al.</i> , "Alpha-MSH Peptides Inhibit Acute Inflammation and Contact Sensitivity," <i>Peptides</i> , 11:979-982 (1990). |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s). | |

| | | | | | |
|---|---|----|----|--------------------------|-------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary) | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/659,053 |
| | | | | Confirmation Number | |
| | | | | Filing Date | September 8, 2003 |
| | | | | First Named Inventor | James M. LIPTON |
| | | | | Group Art Unit | |
| Examiner Name | | | | | |
| Sheet | 7 | of | 11 | Attorney Docket No. | 54275.8005.US03 |

| | |
|-----|--|
| C55 | HILTZ, M.E., <i>et al.</i> , "α-MSH Peptides Inhibit Acute Inflammation Induced in Mice by rIL-1β, rIL-6, rTNF-α and endogenous pyrogen but not that cause by LTB ₄ , PAF and rIL-8," <i>Cytokine</i> 4(4):320-328 (1992). |
| C56 | HOLDEMAN, M., <i>et al.</i> , "Antipyretic Activity of a Potent α-MSH Analog," <i>Peptides</i> 6, 273-5 (1985). |
| C57 | HUANG, <i>et al.</i> , "Role of central melanocortins in endotoxin-induced anorexia," <i>Am. J. Physio (Regulatory, Integrative & Comparative Physiology)</i> , Vol. 276, No. 3, pgs R864-R871 (1999). |
| C58 | HUBERSPITZ <i>et al.</i> , "Corneal Ulceration: An Update from a Specialized Ambulatory Care Centre." <i>Klinische. Monats. Augen.</i> 200: 251-256 (1992). |
| C59 | HUH S-K., <i>et al.</i> , "The protective effects of α-melanocyte stimulating hormone on canine brain stem ischemia," <i>Neurosurgery</i> 40:132-139, (1997). |
| C60 | ICHIYAMA, T., <i>et al.</i> , "Systemically administered α-melanocyte-stimulating hormone peptides inhibit NF-κB activation in experimental brain inflammation," <i>Brain Research</i> 836: 31-37, (1999). |
| C61 | ICHIYAMA, T., <i>et al.</i> , "α-Melanocyte-stimulating hormone inhibits NF-κB activation and IκBα degradation in human glioma cells and in experimental brain inflammation," <i>Experimental Neurology</i> 157:359-365, (1999). |
| C62 | ICHIYAMA, T., <i>et al.</i> , "Autocrine α-melanocyte-stimulating hormone inhibits NF-κB activation in human glioma cells," <i>Journal of Neuroscience Research</i> 58:684-689,(1999). |
| C63 | ICHIYAMA, T., <i>et al.</i> , "NF-κB activation is inhibited in human pulmonary epithelial cells transfected with α-melanocyte-stimulating hormone vector," <i>Peptides</i> 21: 1473-1477, (2000). |
| C64 | ICHIYAMA, T., <i>et al.</i> , "Inhibition of peripheral NF-κB activation by central action of α-melanocyte-stimulating hormone," <i>Journal of Neuroimmunology</i> 99: 211-217, (1999). |
| C65 | ISHIBASHI & KAUFMAN, "The Effects of Subconjunctival Miconazole in the Treatment of Experimental <i>Candida</i> Keratitis in Rabbits." <i>Arch. Ophthalmol.</i> 103: 1570-1573 (1985). |
| C66 | KHURSHID, M.A., <i>et al.</i> , "Staphylococcus aureus with Reduced Susceptibility to Vancomycin -- Illinois, 1999," <i>Morbidity and Mortality Weekly Report</i> , 48(51): 1165-1167 (2000), < http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4851a1.htm >. |
| C67 | LAZARUS <i>et al.</i> , "An <i>in vitro</i> Method Which Assesses Corneal Epithelial Toxicity due to Antineoplastic, Apreservative and Antimicrobial Agents." <i>Lens Eye Toxic. Res.</i> 6: 59-85 (1989). |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s). | |

| | | | | | |
|---|---|----|----|--------------------------|-------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary) | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/659,053 |
| | | | | Confirmation Number | |
| | | | | Filing Date | September 8, 2003 |
| | | | | First Named Inventor | James M. LIPTON |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 8 | of | 11 | Attorney Docket No. | 54275.8005.US03 |

| | |
|-----|---|
| C68 | LEEMING, "Treatment of Ocular Infections with Topical Antibacterials." <i>Clin. Pharmacokinet.</i> 37: 351-360 (1999). |
| C69 | LEIBOWITZ <i>et al.</i> , "Human Conjunctivitis: Diagnostic Evaluation." <i>Arch. Ophthalmol.</i> 94: 1747-1749 (1976). |
| C70 | LICHTENSTEIGER, W., <i>et al.</i> , "Differential Response of Dopamine Neurons to α -Melanotropin and Analogues in Relation to Their Endocrine and Behavioral Potency," <i>Life Sci.</i> 25:2079-2087 (1979). |
| C71 | LIPTON, J.M., <i>et al.</i> , "Anti-inflammatory Effects of the Neuropeptide α -MSH in Acute Chronic and Systemic inflammation," <i>Ann. N.Y. Acad. Sci.</i> 741, 137-148 (1994). |
| C72 | LIPTON, J.M., <i>et al.</i> , "Anti-inflammatory Actions of the Neuroimmunomodulator α -MSH," <i>Immunol. Today</i> 18, 140-145 (1997). |
| C73 | LIPTON, J.M., "Neuropeptide α -Melanocyte-Stimulating Hormone in Control of Fever, the Acute Phase Response, and Inflammation," <i>Neuroimmune Networks: Physiology and Diseases</i> , (Alan R. Liss, Inc. 1989) pp. 243-250 |
| C74 | LIPTON, J.M., "Modulation of Host Defense by the Neuropeptide α -MSH," <i>The Yale Journal of Biology and Medicine</i> 63: 173-182 (1990). |
| C75 | LIPTON, J.M., <i>et al.</i> , "Marshaling the anti-inflammatory influence of the neuroimmunomodulator α -MSH," <i>News Physiol. Sci.</i> 15: 192-195, (2000). |
| C76 | LIPTON, J.M., <i>et al.</i> , "The neuropeptide α -MSH: a modulator of host reactions," <i>Seminars in Clinical Immunology</i> 10: 25-29, (1995). |
| C77 | LIPTON, <i>et al.</i> , "Mechanisms of antiinflammatory action of the neuro immunomodulatory peptide alpha-MSH," <i>Annals of the N.Y. Acad. Sci.</i> , vol. 840, pgs. 373-380 (1998). |
| C78 | LOETSCHER, <i>et al.</i> , "N-terminal Peptides of Stromal Cell-derived Factor-1 with CXC Chemokine Receptor 4 Agonist and Antagonist Activities." <i>J. Biological Chem.</i> 273(35) 22279-22283 (1998). |
| C79 | LU & CHAN, " <i>Flavobacterium indologenes</i> Keratitis." <i>Ophthalmologica</i> 211: 98-100 (1997). |
| C80 | LUGER, T.A., <i>et al.</i> , "Production of Immunosuppressing Melanotropins by Human Keratinocytes," <i>Ann. N.Y. Acad. Sci.</i> 680: 567-570 (1993). |
| C81 | LYSON, K., <i>et al.</i> , "Binding of Anti-Inflammatory α -Melanocyte-Stimulating Hormone Peptides and Proinflammatory Cytokines to Receptors on Melanoma Cells," <i>Neuroimmunomodulation</i> , 1:121-126 (1994). |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s). | |

| | | | | | |
|---|---|----|----|--------------------------|-------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary) | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/659,053 |
| | | | | Confirmation Number | |
| | | | | Filing Date | September 8, 2003 |
| | | | | First Named Inventor | James M. LIPTON |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 9 | of | 11 | Attorney Docket No. | 54275.8005.US03 |

| | |
|-----|--|
| C82 | MACALUSO, A., <i>et al.</i> , "Antiinflammatory Influences of α -MSH molecules: Central Neurogenic and Peripheral Actions," <i>The Journal of Neuroscience</i> , 14(4): 2377-2382 (1994). |
| C83 | MAYHALL, "Ten Home Remedies for Sunburn," <i>Seasonal Health</i> , (July 14, 2000), < http://drkoop.com/wellness/seasonal/summer/sunburn.html >. |
| C84 | MUGRIDGE, K.G., <i>et al.</i> , " α -Melanocyte-Stimulating Hormone reduces interleukin-1 β effects on rat stomach preparations possibly through interference with type I receptor," <i>European Journal of Pharmacology</i> , 197: 151-155 (1991). |
| C85 | NOISAKRAN, S., <i>et al.</i> , "Lymphocytes Delay Kinetics of HSV-1 Reactivation from in vitro Explants of Latent Infected Trigeminal Ganglia," <i>J. Neuroimmunol.</i> 95(1-2):126-35 (1999). |
| C86 | PATEL, A., <i>et al.</i> , "Herpes Simplex Virus Type 1 Induction of Persistent NF- κ B Nuclear Translocation Increases the Efficiency of Virus Replication," <i>Virology</i> 247(2):212-22 (1998). |
| C87 | POTTS, "Sunlight, Sunburn, and Sunscreens," <i>Postgrad. med.</i> , 87:52-61 (1990). |
| C88 | RAJORA, N., <i>et al.</i> , " α -MSH Modulates Local and Circulating tumor Necrosis Factor α in Experimental Brain Inflammation," <i>J. Neurosci.</i> , 17, 2181-2186 (1997). |
| C89 | RAJORA, N., <i>et al.</i> , " α -MSH Production, Receptors, and Influence on Neopterin, in a Human Monocyte/macrophage Cell Line," <i>J. Leukoc. Biol.</i> 59, 248-253 (1996). |
| C90 | RAJORA, N., <i>et al.</i> , " α -MSH modulates experimental inflammatory bowel disease," <i>Peptides</i> 18:381-385, (1997). |
| C91 | "Remington's Pharmaceutical Sciences," <i>Mack Publishing Co.</i> , 18 th ed. (1990). |
| C92 | RICHARDS, D.B., <i>et al.</i> , "Effect of α -MSH (11-13) (Lysine-Proline-Valine) on Fever in the Rabbit," <i>Peptides</i> 5, 815-817 (1984). |
| C93 | ROBBINS, S. <i>Pathologic Basis of Disease</i> 5 th ed., Saunders Co., Philadelphia p.335-337, 354-355, 1008, 1037-1038. (1994). |
| C94 | RYAN, <i>et al.</i> , "Inflammation," a <i>Scope Publication</i> , The Upjohn Company, (1977). |
| C95 | SATPATHY & VISHALAKSHI, "Ulcerative Keratitis: Microbial Profile and Sensitivity Pattern: A Five Year Study." <i>Ann. Ophthalmol. Glaucoma</i> 27: 301-306 (1995). |
| C96 | STAR, R.A., <i>et al.</i> , "Evidence of Autocrine Modulation of Macrophage Nitric Oxide Synthase by α -MSH," <i>Proc. Nat'l. Acad. Sci. (USA)</i> 92, 8015-8020 (1995). |
| C97 | STEVENS, D.L., "Could Nonsteroidal Anti-inflammatory Drugs (NSAIDs) Enhance Progression of Bacterial Infections to Toxic Shock Syndrome?," <i>Clin. Infect. Dis.</i> 21, 977-80 (1997). |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s). | |

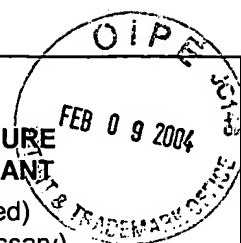
| | | | | | |
|---|----|----|----|--------------------------|-------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT Form PTO-1449 (Modified) (Use several sheets if necessary) | | | | COMPLETE IF KNOWN | |
| | | | | Application Number | 10/659,053 |
| | | | | Confirmation Number | |
| | | | | Filing Date | September 8, 2003 |
| | | | | First Named Inventor | James M. LIPTON |
| | | | | Group Art Unit | |
| | | | | Examiner Name | |
| Sheet | 10 | of | 11 | Attorney Docket No. | 54275.8005.US03 |

| | |
|------|--|
| C98 | SZALAY, K.S., <i>et al.</i> , "Structure-activity studies with ACTH/ α -MSH fragments on corticosteroid secretion of isolated zona glomerulosa and fasciculata cells," <i>Regulatory Peptides</i> , 11: 187-192 (1985). |
| C99 | TAHERZADEH, S., <i>et al.</i> , " α -MSH and its receptors in regulation of tumor necrosis factor- α production by human monocyte/macrophages," <i>Am. J. Physiol.</i> 276: R1289-R1294, (1999). |
| C100 | THODY, A.J., <i>et al.</i> , "MSH Peptides are Present in Mammalian Skin," <i>Peptides</i> 4, 813-815 (1983). |
| C101 | UEHARA, Y., <i>et al.</i> , "Carboxyl-terminal tripeptide of α -Melanocyte-Stimulating Hormone antagonizes interleukin-1-induced anorexia," <i>European Journal of Pharmacology</i> , 220: 119-122 (1992). |
| C102 | VAN NISPEN, J.W., <i>et al.</i> , "Structure-Activity Relationships of Peptides Derived From ACTH, β -LPH and MSH With Regard To Avoidance Behavior in Rats," <i>Pharmac. Ther.</i> 16: 67-102 (1982). |
| C103 | WALEV, I., <i>et al.</i> , "Enhancement by TNF- α of Reactivation and Replication of Latent Herpes Simplex Virus from Trigeminal Ganglia of Mice," <i>Arch Virol.</i> 140(6):987-92 (1995). |
| C104 | WATANABE, T., <i>et al.</i> , "Inhibition of IL-1 β -induced peripheral inflammation by peripheral and central administration of analogs of the neuropeptide α -MSH," <i>Brain Research Bulletin</i> 32: 311-314, (1993). |
| C105 | WEISS, <i>et al.</i> , "Corticotropin-peptide regulation of intracellular cyclic-AMP production in cortical neurons in primary culture," <i>J. Neurochem.</i> Vol. 45, No. 3, pgs 869-874 (1985). |
| C106 | WENZEL, R.P., <i>et al.</i> , "Candida Species: Emerging Hospital Bloodstream Pathogens," <i>Infect. Control. Hosp. Epidemiol.</i> 12: 523-4 (1991). |
| C107 | WILKINS <i>et al.</i> , "Penicillin-Resistant <i>Streptococcus pneumoniae</i> Keratitis." <i>Cornea</i> 15: 99-100 (1996). |
| C108 | WONG, K.Y., <i>et al.</i> , "A Potential Mechanism of Local Anti-inflammatory Action of Alpha-Melanocyte-Stimulating Hormone within the Brain: Modulation of Tumor Necrosis Factor-Alpha Production by Human Astrocytic Cells," <i>Neuroimmunomodulation</i> , 4:37-41 (1997). |
| C109 | "Vaginitis," <i>National Institute of Child Health and Human Development - Publications On-line</i> (last modified January 12, 2000). < www.nichd.nih.gov/publications/pubs/vagtoc.html > |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application(s). | |

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Form PTO-1449 (Modified)
(Use several sheets if necessary)



COMPLETE IF KNOWN

| | |
|----------------------|-------------------|
| Application Number | 10/659,053 |
| Confirmation Number | |
| Filing Date | September 8, 2003 |
| First Named Inventor | James M. LIPTON |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket No. | 54275.8005.US03 |

| | | | |
|-------|----|----|----|
| Sheet | 11 | of | 11 |
|-------|----|----|----|

| | |
|------|---|
| C110 | "Tampons and Asbestos, Dioxins, & Toxic Shock Syndrome," <i>FDA Center for Devices and Radiological Health</i> (July 23, 1999), < http://www.fda.gov/cdrh/ocd/tamponsabs.html > |
| C111 | "Women's Health, Urinary Tract Infections: A Patient's Guide to Treatment," <i>AMA Health Insight, On-Line Health Information for Everyone</i> (last updated October 30, 1998) < http://www.ama-assn.org/insight/h_focus/wom_hlth/uti/uti.htm >. |
| | |

| | |
|--|-----------------|
| EXAMINER | DATE CONSIDERED |
| *EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to application(s). | |